510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K041748

B. Purpose for Submission:
New use, new device

C. Analyte:
Human chorionic gonadotropin

D. Type of Test:
Qualitative

E. Applicant:
AZOG, Inc.

F. Proprietary and Established Names:
AZOG, Inc. hCG One-Step Urine Home Pregnancy Test (DipStick, Cassette and Midstream)

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155
2. Classification:
   II
3. Product Code:
   LCX
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   The AZOG hCG One-Step (Urine) Pregnancy Home Test (DipStick, Cassette and Midstream) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy at home.
2. Indication(s) for use:
   AZOG, Inc. hCG One-Step Urine Home Pregnancy Test (DipStick, Cassette and Midstream) is intended for the qualitative determination of human chorionic gonadotropin (hCG) in human urine. The test is for over-the-counter and professional use. The test is for the early detection of pregnancy.
3. Special condition for use statement(s):
   This device is intended for over-the-counter use.
4. Special instrument Requirements:
   None

I. Device Description:
The device is an immunochromatographic device containing monoclonal (murine) anti-hCG coated particles and polyclonal (caprine) anti-hCG coated on the

membrane. The device is supplied in the following formats with each individual test sealed in a foil pouch: dipstick, cassette, and midstream.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   AZOG, Inc. hCG One-Step Urine Pregnancy Test (DipStick and Cassette)
2. Predicate K number(s):
   K022680 and K022681
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Qualitative determination of hCG in urine	Same
Principle	Chromatographic immunoassay	Same
Differences		
Item	**Device**	**Predicate**
Intended Use	OTC and professional use	Professional use
Test Formats	Dipstick, cassette, and midstream	Dipstick and cassette

K. Standard/Guidance Document Referenced (if applicable):
None referenced

L. Test Principle:
The device is a chromatographic immunoassay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
      Not applicable
   b. *Linearity/assay reportable range:*
      Not applicable
   c. *Traceability (controls, calibrators, or method):*
      WHO Third International Standard
   d. *Detection limit:*
      See K022680 and K022681.
   e. *Analytical specificity:*
      See K022680 and K022681.
   f. *Assay cut-off:*
      See K022680 and K022681.
2. Comparison studies:
   a. *Method comparison with predicate device:*
      Sixty (60) clinical urine specimens (30 positive and 30 negative) were assayed on both the AZOG, Inc. hCG One-Step Urine Pregnancy Test (Midstream) and the AZOG, Inc. hCG One-Step

Urine Pregnancy Test (Cassette). Multiple lots of the midstream test were evaluated. The results demonstrated 100% agreement between the two devices (>99% accuracy when compared to the predicate).

b. Matrix comparison:
Not applicable

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a and b are not applicable):
   One hundred (100) female subjects, eighteen years of age or older, who had completed seventh grade or higher educational level, participated in a usability study. Some of the subjects were known positives; however, the majority may have suspected pregnancy.

   Subjects were randomly assigned to use one of the three test formats as follows: 28 subjects performed the test strip, 32 subjects performed the cassette, and 40 subjects performed the midstream procedure. Each subject noted their interpretation of the results, and then forwarded a sample of their urine to the professional who performed a second test to assess accuracy and repeatability of results. The professional used the same test version (cleared for professional use) as the subject's OTC test, except in the case of the midstream test, in which the professional test strip version (DipStick) was used.

   One hundred percent (100%) agreement between the subject's and the professional's result was observed for both the DipStick and the Cassette. For the comparison between the new test and the DipStick, the new test yielded two false positives and one false negative. One sample producing an "invalid" result was thrown out. Therefore, the accuracy of the new test was 92.31% when compared with the predicate.
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   See K022680 and K022681.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.